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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448

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EXAMINER

AHMED, AAMER S

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/759,695

Applicant(s)

DIPIANO ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fallon et al U.S. Patent Number 6,027,471, in view of Yeager U.S. 6,224,573 and further in view of Quintero U.S. Patent Number 6,547,467.

Fallon et al discloses an apparatus and method for applying an agent comprising an applicator barrel (12), wherein the barrel comprises a medication chamber (18) at the proximal end of the applicator, and wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber (col. 2 line 37); a plunger (22), wherein the plunger is insertable in telescoping relation to the applicator barrel; a plunger tip

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(38), wherein the plunger tip is at the end of the plunger; and wherein the applicator comprise a flange (44).

Fallon fails to explicitly disclose that the method is for transvaginal delivery of a cream pharmaceutical composition nor that the device is filled from the tip at a volume of less than 1 ml and a cap having a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel forming an air-tight seal with the applicator barrel and the plunger tip forms an air-tight seal with the applicator barrel.

Yeager et al discloses a similar device and a method for delivering a drug tranvagianlly (col. 1 line 56), the device including an applicator cap (12) is attached to the applicator barrel forming an air-tight seal with the applicator barrel (col. 3) and the plunger tip forms an air-tight seal with the applicator barrel (col. 6), wherein the pharmaceutical delivered is a cream (col. 1 line 48). Yeager et al further discloses a similar method in which the pharmaceutical formulation is in an amount effective to treat diseases of the female urogenital system (col. 2).

Quintero discloses a similar invention wherein the applicator is filled from the tip with a volume of less than 1 ml (see col. 18 line 1 and col. 7 line 27).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Fallon et al by incorporating the cap and air-tight seal as taught by Yeager et al and the method of filling the applicator from the tip as taught by Quintero in order to prevent infection and keep the barrel compartment sterile.

*Response to Arguments*

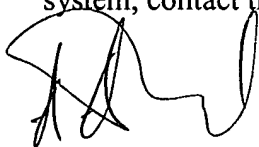
Applicant's arguments with respect to claims 1-6, 8-10 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



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